Division of Environmental Health
Maine Center for Disease Control and Prevention
Department of Health & Human Services

Environmental & Occupational Health Program

Interdepartmental Memo

To: David Wright, DEP

From: Pamela Wadman, MeCDC

cc: Andrew E. Smith, ScD, MeCDC

Date: August 17, 2016

Re: Human Health Risk-Based Screening Levels for Pe rfluoroalkyl Compounds

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As requested by DEP, MeCDC has derived human health risk-based screening levels for three perfluoroalkyl substances (PFAS): perfluorooctanoic acid (PFOA), perfluorooctane sulfonate (PFOS) and perfluorobutane sulfonate (PFBS). Maine had derived screening levels (SLs) for PFOA and PFOS in 2014, this is an update to reflect recent advances in PFAS toxicology. SLs have been developed for exposures to soil, sediment, groundwater, surface water, and for the ingestion of fish.

1 PFAS Toxicity Information

EPA's Integrated Risk Information System (IRIS) toxicological database does not have toxicity information for these three PFAS, therefore toxicity information was obtained from other EPA sources as described below. Noncancer risk-based SLs are derived by estimating a receptors exposure and comparing it to a toxicological reference dose (RfD). An RfD is an estimate of a daily oral exposure that is likely to be without an appreciable risk of deleterious effects during a lifetime[1].

1.1 RfD for PFOA

The RfD for PFOA is presented in the 2016 Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA)[2] (EPA 2016a). The PFOA RfD is derived from a developmental toxicity study in mice; the critical effects included reduced ossification in proximal phalanges and accelerated puberty in male pups

[1] https://www.epa.gov/iris/reference-dose-rfd-description-and-use-health-risk-assessments
[2] https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_health_advisory_final-plain.pdf

following exposure during gestation and lactation. Because the developing fetus and newborn are particularly sensitive to PFOA-induced toxicity, the RfD based on developmental effects also is protective of adverse effects in adults (e.g., liver and kidney toxicity). The PFOA RfD of $2x10^{-5}$ mg/kg-day utilized pharmacokinetic modelling to estimate human equivalent dose from a mouse study and is based on a Lowest Observed Effect Adverse Level (LOAEL) with a combined uncertainty factor (UF) of 300.

1.2 RfD for PFOS

The RfD for PFOS is presented in the 2016 Drinking Water Health Advisory for Perfluorooctane Sulfonate (PFOS)[3] (EPA 2016b). The RfD for PFOS is derived from a developmental toxicity study in rats; the critical effect was decreased pup body weight following exposure during gestation and lactation. The RfD of $2x10^{-5}$ mg/kg-day is based upon a human equivalent dose No Observed Effect Adverse Level (NOAEL) with a combined UF of 30.

1.3 RfD for PFBS

A RfD for PFBS has been published by EPA's Provisional Peer-Reviewed Toxicity Values (PPRTV) program[4] (EPA 2014a). A PPRTV is a toxicity value derived for use in the Superfund Program when such value is not available in EPA's IRIS. Chronic and subchronic RfDs for PFBS were derived based on a dosimetrically- adjusted benchmark dose level ($BMDL_{10}$) for kidney hyperplasia from a subchronic gavage study in rats. The subchronic RfD of $2E^{-1}$ mg/kg-day has a combined uncertainty factor of 100(10 for intraspecies sensitivity, an 3 each for database deficiency and interspecies toxicodynamics). The chronic RfD of $2x10^{-2}$ mg/kg-day is based on the same value with and added UF of 10 to adjust for subchronic duration for a combined UF of 1000.

2 Screening Level Derivation

SLs were derived using "Guidance for Human Health Risk Assessments for Hazardous Substance Sites in Maine" (DEP 2011). Additional technical support documents, including Maine-specific exposure factors, are described for each media below. Where applicable, SLs include ingestion, dermal and inhalation pathways. Inhalation SLs were not calculated for the PFAS due to the lack of inhalation toxicity information.

[3] https://www.epa.gov/sites/production/files/2016-05/documents/pfos_health_advisory_final-plain.pdf
[4] https://hhpprtv.ornl.gov/issue_papers/PotassiumPerfluorobutaneSulfonate.pdf

Potential receptors for exposure to PFAS in soil include the resident, the recreational user, and commercial and construction workers. Surface water and sediment present a potential exposure pathway for the recreational user (wading or swimming) and the construction worker. SLs for residential groundwater exposure are the Maine Maximum Exposure Guidelines for Drinking Water, which are based on ingestion, with incorporation of an allowance for other potential exposure pathways. Groundwater exposure for the construction worker includes both ingestion and dermal exposures. The media specific SLs for both soil and sediment, and both ground water and surface water for the construction worker are equivalent due to the use of consistent exposure assumptions for these media.

2.1 Soil

The methodology used for the derivation of soil and sediment SLs is presented in "Technical Basis and Background for the 2013 Maine Screening Levels for Soil Contaminated with Hazardous Substances" (DEP 2013). Soil SLs are presented in Table 2.1. The soil SL calculations with equations and exposure parameters are presented in Appendix 1.

Table 2.1. Soil Screening Levels for Perfluorinated Compounds (mg/kg)

	Resident	Park User	Outdoor Commercial Worker	Excavation or Construction Worker
PFBS	3407	5678	10,000	10,000
PFOA	2.7	4.4	21	4.8
PFOS	2.7	4.4	21	4.8

mg/kg – milligrams per kilogram

2.2 Sediment

Sediment SLs incorporate the ingestion and dermal contact pathways for adult and child recreational exposure scenarios, as described in the "Technical Basis and Background for the 2013 Maine Screening Levels for Soil Contaminated with Hazardous Substances" (DEP 2013). Sediment SLs are presented in Table 2.2. The sediment SL calculations, equations and exposure parameters are presented in Appendix 2

Table 2.2. Sediment Screening Levels for Perfluorinated Compounds (mg/kg)

	Recreational Child Wading	Recreational Adult Wading	**Recreational Sediment Screening Level[1]**
PFBS	6551	65513	6551
PFOA	5	47	5
PFOS	5	47	5

[1] The recreational sediment screening level is the lower of the adult and child screening levels.

2.3 Groundwater

SLs for groundwater exposure were developed for the resident and the potential future construction worker. For the residential groundwater exposure pathway, SLs were derived in accordance with Maine CDC procedures for development of Maximum Exposure Guidelines (MeCDC 2011) The methodology for derivation of construction worker groundwater SLs is presented in Wilcox and Barton, Inc., "Development of Construction Worker Groundwater Screening Levels (RAGs), June 21, 2012 (Wilcox and Barton 2012). In deviation from the Wilcox and Barton methodology, the groundwater exposure time was changed from 20 minutes per day to 8 hours per day, in agreement with the construction worker surface water exposure time presented in the Standard Default Exposure Assumptions for Maine Risk Assessments (DEP 2013b). Groundwater SLs are presented in Table 2.3. The groundwater SL calculations with equations and exposure parameters are presented in Appendix 3.

Table 2.3. Groundwater Screening Levels for Perfluorinated Compounds (ug/L)

	Resident	**Construction Worker**
PFBS	140	795,695
PFOA	0.12	0.74
PFOS	0.12	1.33

ug/L = microgram per liter

2.4 Surface Water

Surface water SLs were derived for ingestion and dermal contact, for both adult and child recreational wading and swimming exposure scenarios, as presented in the Guidance for Human Health Risk Assessments for Hazardous Substance Sites in Maine (DEP 2011).

The dermal-water pathway was included in the surface water exposure scenario as recommended in the EPA Risk Assessment Guidance (RAGs) for Superfund Volume 1 (Part E, Supplemental Guidance for Dermal Risk Assessment) (EPA 2004). The dermal water pathway for PFAS is complicated because the compounds' surfactant properties make estimation of the octanol-water partition coefficient (Kow) difficult (Arp et al. 2006). EPA has stated that Kow values for PFOA and PFOS are not measurable (EPA 2013). Due to known inconsistencies in experimentally measured Kow values for PFAS, it is appropriate to utilize Kow values estimated based upon chemical structure. Consistent with EPA practice, Kow values for PFOA and PFOS were estimated using the Estimation Program Interface (EPI) Suite, as cited in Arp and Goss (2006). The RAGS Part E dermal guidance includes a discussion of uncertainty that is introduced when an estimated octanol-water partition coefficient (K_{ow}) is outside of the Effective Prediction Domain (EPD) for estimation of the dermal permeability coefficient using the Potts and Guy equation. However, without an alternative, the EPA recommendation is to include the dermal water exposure pathway for compounds with Kow values outside the EPD (EPA 2004, page A-4). If the surface water SL's thus calculated trigger inclusion of PFAS in a risk assessment, the dermal water pathway may be discussed in the uncertainty section (EPA 2004, page 6-2). Surface water SLs are presented in Table 2.4. The surface water SL calculations with equations and exposure parameters are presented in Appendix 4.

Table 2.4. Surface Water Screening Levels for Perfluorinated Compounds (ug/L)

	Child Wading	Child Swimming	Adult Wading	Adult Swimming	**Recreational Surface Water SL[1]**	**Construction Worker SL[2]**
PFBS	7914	11950	94418	103918	7914	795,695
PFOA	0.20	0.17	1.45	0.90	0.17	0.74
PFOS	0.36	0.30	2.59	1.62	0.30	1.3

ug/L = microgram per liter
1. Recreational surface water screening level is the lowest of the adult and child screening levels.
2. The construction worker surface water exposure is the same a groundwater exposure.

2.5 Fish Tissue

Fish tissue SLs were developed using the approach presented in the Maine CDC document "Bureau of Health Fish Tissue Action Levels" (MeCDC 2001). Screening levels were developed using the upper level fish ingestion rate for Maine recreational anglers, 32.4 grams/day (one eight ounce meal per week). In addition, SLs were developed using the federal Superfund ingestion rate of 54 grams/day for consumption of locally caught fish, and 132 grams/day for subsistence fishermen (EPA 2014b). Fish tissue SLs are presented in Table 2.5. The fish tissue SL calculations with equations and exposure parameters are presented in Appendix 5.

Table 5. Fish Tissue Screening Levels (ug/kg)

Consumer	Maine Recreational Angler	EPA Recreational Fisher	Subsistence Fisher
Ingestion rate source	Maine CDC	EPA 2014b	EPA 1991
Fish meals per week	1	2	4
Ingestion rate - grams/day	32	54	132
PFBS	43,750	25,926	10,606
PFOA	44	26	11
PFOS	44	26	11

ug/kg = microgram per kilogram

3 References

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DEP 2013. Technical Basis and Background for the 2013 Maine Screening Levels for Soil Contaminated with Hazardous Substances. Available at: http://www.maine.gov/dep/ftp/RAGS-Background-Documents/

DEP 2013b Standard Default Exposure Assumptions for Maine Risk Assessments. Available at http://www.maine.gov/dep/spills/publications/guidance/index.html

EPA 1991 Risk Assessment Guidance For Superfund Volume I: Human Health Evaluation Manual Supplemental Guidance "Standard Default Exposure Factors" (1991) available at: http://www.epa.gov/oswer/riskassessment/pdf/oswer_directive_9285_6-03.pdf

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